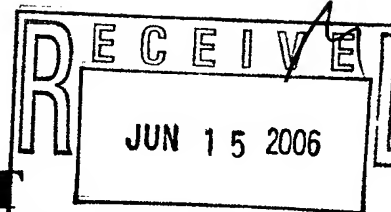


KW03-001A-04-~~PCT~~ PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
LAURA A. CORUZZI
JONES DAY
222 EAST 41ST STREET
NEW YORK, NY 10017-6702



PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year)

12 JUN 2006

Applicant's or agent's file reference

10165-28-228 ✓

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/13099

26 April 2004 (26.04.2004)

25 April 2003 (25.04.2003)

Applicant

THE KENNETH & WARREN INSTITUTE, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US

Mail Stop PCT, Attn: IPEA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

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Authorized officer

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Telephone No. 571-272-1600

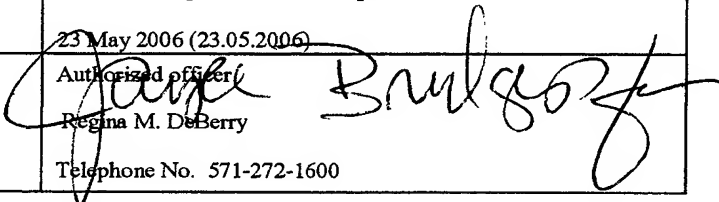
PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 10165-28-228	FOR FURTHER ACTION	See Form PCT/IPEA/416																								
International application No. PCT/US04/13099	International filing date (day/month/year) 26 April 2004 (26.04.2004)	Priority date (day/month/year) 25 April 2003 (25.04.2003)																								
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 514/2;530/397,399;435/7.1,7.8,69.1,325,320.1;424/134.1																										
Applicant THE KENNETH & WARREN INSTITUTE, INC.																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <div style="margin-left: 40px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																										
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 16 November 2004 (16.11.2004)	Date of completion of this report 23 May 2006 (23.05.2006)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	<div style="text-align: center;">  Authorized officer Regina M. DeBerry Telephone No. 571-272-1600 </div>																									

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-123 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 124-136 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the drawings:
pages 1-15 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/13099**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>31, 32, 41, 51, 81-83</u>	YES
	Claims <u>1-30, 33-40, 42-50, 52-80</u>	NO
Inventive Step (IS)	Claims <u>31, 32, 41, 51, 81-83</u>	YES
	Claims <u>1-30, 33-40, 42-50, 52-80</u>	NO
Industrial Applicability (IA)	Claims <u>1-83</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-30, 33-40, 42-50, 56-80 lack novelty under PCT Article 33(2) as being anticipated by D'Andrea et al., US 5,278,065. D'Andrea et al. teach DNA encoding erythropoietin receptor (EPO-R) that can be used to define EPO/EPO-R complex to define those proteins which interact with the EPO/EPO-R complex to transduce a proliferative and maturation signal to EPO sensitive cells (column 3, lines 1-15). D'Andrea *et al.* teach DNA encoding EPO-R and methods of producing erythropoietin receptor (EPO-R). D'Andrea et al. teach host cells that can be transfected with DNA encoding EPO-R. The cells include eukaryotic and prokaryotic cells (column 4, line 60-column 6, line 34). D'Andrea et al. teach fusion proteins of EPO-R comprising various fragments of the receptor (column 7, lines 1-19). D'Andrea et al. teach methods of treatments using EPO-R to screen for agents possessing EPO activity. D'Andrea et al. teach compounds identified as having EPO activity, which may be suitable as alternatives to EPO (column 7, lines 20-34). D'Andrea et al. teach that EPO-R may be used in binding assays, wherein EPO is labeled (column 10, line 55-column 11, line 34 and column 14, lines 41-64). D'Andrea et al. teach the use of cells that endogenously express EPO-R (column 11, lines 60-68). D'Andrea et al. teach various forms of administration of a pharmaceutical compositions (column 7, lines 35-68). D'Andrea et al. teach the inhibition of EPO binding to EPO-R by antibodies (column 11, lines 36-59) and a secreted receptor (column 20, lines 55-64). D'Andrea et al. teach the biological activity of EPO-R via thymidine incorporation (column 18, line 50-column 19, line 3).

Claims 52-63, 65-80 lack novelty under PCT Article 33(2) as being anticipated by Bennett et al., US 5,997,865. Bennett et al. teach the production of agonist antibodies against the flk2/flt3 receptor for enhancing proliferation. Bennett et al. teach the use of labeled antibodies to detect the receptor in biological samples (column 4, lines 41-50 and column 9, lines 14-34). Bennett et al. teach the use of ELISA binding assays to screen for binding specificity. Bennett et al. teach that the treatment can be combined with EPO (column 15, lines 50-66). Bennett et al. teach the stimulating proliferation of activity of an antibody made against the cytokine receptor (column 26, line 60-column 27, line 12).

Claims 31, 32, 41, 51 and 81-83 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed invention.

Claims 1-83 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/13099

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

a. type of material

- ☒ a sequence listing
☒ table(s) related to the sequence listing

b. format of material

- ☒ on paper
☐ in electronic form

c. time of filing/furnishing

- ☒ contained in the international application as filed
☐ filed together with the international application in electronic form
☒ furnished subsequently to this Authority for the purposes of search and/or examination
☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/13099

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of IPC:

A61K 38/19(2006.01),39/00(2006.01);C07K 14/52(2006.01),14/505(2006.01);G01N 33/53(2006.01);C12N 5/00(2006.01),15/00(2006.01)